Recommendation:-

The MDAC (**Cardiovascular**) deliberated the proposals on **18.09.2012** and recommended the following:

Agenda No.	File No.	Name of the Proposed Device	Recommendations
1.	4-MD/CT-76/2012-DC	**<u>Type of the Mechanical Valve Implants:</u>** **1.On-X Prosthetic Heart Valve (Aortic & Mitral)** **2. SJM Mechanical Heart Valve (Aortic & Mitral)**	The committee after deliberation recommended following needs to be clarified/submitted before further course of action: 1. Need to submit amended protocol giving the exact number of subjects and sites enrolling globally. 2. Scientific justification for enrolling the 30% patients in India of total patients globally recruited. 3. Trial should be preferably include the equal no. of sites from the Government institution 4. The devices under Investigation / trial including treatment aspects should be provided free of cost to the patients enrolling in the study. 5. Recruitment period (enrolling first patient and last patient) in the said study should be well defined. 6. Compensation clause need to be changed, as per the CDSCO Guidelines 7. Procedure related complications are to be included in the compensation. 8. Ethics committee approval from each site is required. 9. Regulatory approval from each site globally.

Recommendation:-

The MDAC (**Cardiovascular**) deliberated the proposals on **17.09.2012** and recommended the following:

Agenda No.	File No.	Name of the Device	Recommendation
1.	4-MD/CT-80/2012-DC	**"Symplicity™ Renal denervation system"**	The committee after deliberation recommended that the clinical trial permission should be given with the following condition: • Patients follow up after five months also to be included in the protocol. • Compensation clause need to be changed, as per the CDSCO Guidelines. • Procedure related complication are to be included in the compensation clause. • Trial should be carried out on the preferably equal no. of sites from the Government Institution.

Recommendation:-

The MDAC (**Cardiovascular**) deliberated the proposals on **08.08.2012** and recommended the following:

Agenda No.	File No.	Name of the firm & the product name	Recommendation
1.	4-MD/CT-42/2010-DC	**Everolimus Eluting Bioresorbable Vascular Scaffold(Stent**)	The Committee recommended that the data generated from the study "Absorb Extend Clinical Investigation: A continuation in the clinical Evaluation of the Abbott Vascular Everolimus Eluting Bioresorbable Vascular Scaffold in the treatment of subjects de novo native coronary artery lesions" can be considered for the approval of the ABSORB BVS system subject to the following conditions:- • Long term (12, 18 and 24 months) data of 100 subjects should be submitted for further quality of the device. • As Post Market Surveillance, the firm should submit Periodic Safety Reports every Six Months for the first two years. For subsequent two years, the Periodic Safety Reports should be submitted annually.